FH

STATE OF WISCONSIN
Division of Hearings and Appeals

In the Matter of

[redacted]

DECISION

MPA/170347

PRELIMINARY RECITALS

Pursuant to a petition filed November 27, 2015, under Wis. Stat. § 49.45(5), and Wis. Admin. Code § HA 3.03(1), to review a decision by the Division of Health Care Access and Accountability in regard to Medical Assistance, a hearing was held on December 21, 2015, at Chippewa Falls, Wisconsin.

The issue for determination is whether the petitioner is entitled medical assistance reimbursement for an autologous stem cell transplant

There appeared at that time and place the following persons:

PARTIES IN INTEREST:
Petitioner:

[redacted]

Respondent:

Department of Health Services
1 West Wilson Street, Room 651
Madison, Wisconsin 53703
By: [redacted], M.D.
Division of Health Care Access and Accountability
1 West Wilson Street, Room 272
P.O. Box 309
Madison, WI 53707-0309

ADMINISTRATIVE LAW JUDGE:
Michael D. O'Brien
Division of Hearings and Appeals

FINDINGS OF FACT

1. The petitioner is a resident of Chippewa County.
2. The petitioner is a 51-year-old man diagnosed with plasma cell leukemia in 2013.
3. The petitioner had a double-cell allogenic stem cell transplant in May 2014.

4. The petitioner's leukemia went into remission after his 2014 stem cell transplant but recurred in September 2015.

5. As of November 14, 2015, the petitioner had completed "2 months of RVD chemotherapy with evidence of response." [redacted] *Progress Notes,* November 14, 2015, p.3.

6. The petitioner's physician indicated that the petitioner is responding well to chemotherapy and recommended that he continue with this. *Id.,* p.4.

7. On November 20, 2015, the petitioner requested an autologous stem cell transplant. The cost of the procedure is approximately $100,000. The Office of Inspector General denied the request on November 24, 2015.

8. There is no evidence that the requested transplant will extend the petitioner's life. Nor is there any evidence concerning the affect the transplant will have on the quality of his life.

DISCUSSION

The petitioner is a 51-year-old man who was diagnosed with plasma cell leukemia in 2013. His cancer went into remission after he received a double-cell allogenic stem cell transplant in May 2014. An allogenic transplant is one received from another person. In September 2015, his leukemia recurred. Since then, he has received RVD chemotherapy. He and his provider, [redacted], request an autologous stem cell transplant under Wis. Admin. Code, § DHS 107.06. This type of transplant involves harvesting a person's own stem cells and later putting them back into the person's body. The Office of Inspector General denied the request because it contends the procedure is not effective for those who have already received a stem cell transplant.

The department does not cover services it determines are "unreliable" or "ineffectual." Wis. Admin. Code, § DHS 107.03(5). In this matter it relied upon a report by a physician employed by [redacted], a private company the state has hired to review complex questions of medical necessity. It quotes a statement by [redacted]'s physician contending that medical research does not support the request:

> There is no (evidence in the) literature to support the use of autologuous transplant following all transplant for plasma cell leukemia. The is some data to support allo transplant following auto, but that is somewhat controversial and is probably inferior to tandem auto transplant for this disease. Even delayed tandem auto transplant is not shown to have any benefit in this entity although it may prolong survival in typical cases of myeloma.

Quoted in letter from Dr. [redacted], December 1, 2015, p.2.

The Office of Inspector General added "an auto transplant using what are essentially donor cells could pose a significant risk to the patient, which is why allogenic transplants are not typically repeated." The letter then quoted the [redacted] doctor as concluding, "As eluded [sic] to by the requesting physician, the use of a novel chemotherapy agents and maintenance chemotherapy would be a much more reasonable approach in this patient." *Id.*

The problem with the Office of Inspector General's submission is that it never refers to any reports or actual medical evidence supporting its position. In fact, it does not even present a copy of the report by the [redacted] doctor or give that doctor's name. Hearsay is admissible in administrative hearings, but it must have some probative value. There is no probative value in a written submission that relies entirely upon selective quotes of an unnamed source who in turn does not identify the basis of his or her opinion. This is not evidence but rather merely an unsupported conclusion whose validity I cannot objectively judge.

But these flaws do not relieve the petitioner of his obligation to prove by the preponderance of the credible evidence that the requested transplant is necessary. His primary physician for the requested treatment, Dr. [redacted], an assistant professor at the [redacted] Medical School, seemed to be at least initially skeptical of the transplant. He stated that because the petitioner had a "cord transplant" he did "not think attempting to exploit graft versus disease effect is a particularly promising avenue for controlling his disease at this time." Dr. [redacted] then stated that he was "very encouraged by [the petitioner'] excellent response to primary therapy and treatment with RVD [chemotherapy]." [redacted] *Progress Notes,* November 14, 2015, p.3. Based upon this, he indicated that the petitioner is responding well to chemotherapy and recommended that he continue with this. *Id.,* p.4. But he did add that after the petitioner continued with a total of four to six cycles of chemotherapy, Dr. [redacted] was "inclined" to then attempt to collect stem cells and proceed with an autologous stem cell transplant. However, because "allo followed by auto is NOT commonly performed[,] … I will have to have to research the feasibility and any reports of this." *Id.* [capitalized emphasis in original]. He later reported, "Discussed discussion among [redacted] group and consensus that it would be appropriate to attempt to collect 'autologous' stem cells to treat him with high does melphalan with hopes of cytoreduction and then going on a maintenance strategy for long term control of PCL." *Id.,* p.5.

The [redacted] medical school is one of the best in the country, but it still must support its positions with evidence. Nothing in the request indicates why Dr. [redacted] went from being a skeptic to a supporter of the procedure other than that he talked it over with his colleagues. Like the Office of Inspector General, the provider must support its conclusions with evidence such as published studies. After the hearing, the petitioner submitted a 29-page report from [redacted], which bills itself as an anonymously peer-reviewed evidence-based clinical resource. The petitioner apparently got this from Dr. [redacted] at the [redacted]. It includes Sticky Notes with handwriting I could not read and highlighting by Dr. [redacted] The document does indicate that one successful autologous transplant may be followed by another autologous transplant; I do not find anything that indicates that an allogenic transplant may be followed by an autologous transplant. Perhaps there is no significant difference between the two situations, but I would require expert testimony—or at least a report comprehensible to a lay person—to prove this. There is neither in this matter.

Moreover, nothing the petitioner has submitted at any time addressed how the outcome of the transplant compares with chemotherapy: There is no assertion that the transplant will extend his life or have fewer side effects while he recovers. Nor is the relative cost of each type of therapy mentioned. These are the things upon which even requests for conventional treatment are determined.

At this point, the petitioner has not presented enough medical evidence to prove that the requested transplant is medically necessary. Therefore, I must uphold the denial. Nothing prevents his provider from submitting a new request. If it does and another hearing is held, both the department and the petitioner will be expected to present much more medical evidence to support its position. That evidence must be comprehensible to a lay person. Ideally, both sides would appear at the hearing with lawyers and medical experts, but I cannot order this. Groups such as Disability Rights Wisconsin sometimes help indigent persons in the petitioner's position.

CONCLUSIONS OF LAW

The Office of Inspector General correctly denied the requested stem cell transplant because the petitioner has not shown by the preponderance of the evidence that the request is medically necessary.

THEREFORE, it is **ORDERED**

The petitioner's appeal is dismissed.

REQUEST FOR A REHEARING

You may request a rehearing if you think this decision is based on a serious mistake in the facts or the law or if you have found new evidence that would change the decision. Your request must be **received within 20 days after the date of this decision.** Late requests cannot be granted.

Send your request for rehearing in writing to the Division of Hearings and Appeals, 5005 University Avenue, Suite 201, Madison, WI 53705-5400 **and** to those identified in this decision as "PARTIES IN INTEREST." Your rehearing request must explain what mistake the Administrative Law Judge made and why it is important or you must describe your new evidence and explain why you did not have it at your first hearing. If your request does not explain these things, it will be denied.

The process for requesting a rehearing may be found at Wis. Stat. § 227.49. A copy of the statutes may be found online or at your local library or courthouse.

APPEAL TO COURT

You may also appeal this decision to Circuit Court in the county where you live. Appeals must be filed with the Court **and** served either personally or by certified mail on the Secretary of the Department of Health Services, 1 West Wilson Street, Room 651, Madison, Wisconsin 53703, **and** on those identified in this decision as "PARTIES IN INTEREST" **no more than 30 days after the date of this decision** or 30 days after a denial of a timely rehearing (if you request one).

The process for Circuit Court Appeals may be found at Wis. Stat. §§ 227.52 and 227.53. A copy of the statutes may be found online or at your local library or courthouse.

Given under my hand at the City of Madison,
Wisconsin, this 1st day of February, 2016

\sMichael D. O'Brien
Administrative Law Judge
Division of Hearings and Appeals

State of Wisconsin\DIVISION OF HEARINGS AND APPEALS

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The preceding decision was sent to the following parties on February 1, 2016.

Division of Health Care Access and Accountability